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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,711	04/07/2005	Niklas Ahlborg	102672-103	6727
27267	7590	12/20/2005	EXAMINER	
WIGGIN AND DANA LLP ATTENTION: PATENT DOCKETING ONE CENTURY TOWER, P.O. BOX 1832 NEW HAVEN, CT 06508-1832			GRUN, JAMES LESLIE	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/511,711	Applicant(s) AHLBORG ET AL.	
	Examiner James L. Grun	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/15/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1641

The disclosure is objected to because of the following informalities: page 24, line 18, second occurrence of "although" should be deleted. Appropriate correction is required.

Claim 37 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). The claim has been treated as if dependent upon claim 35.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-40 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, "the" presence lacks antecedent basis.

In claims 2-34, "Sandwich assay" should be --The sandwich assay-- for proper reference to the previously recited claim components.

In claims 4 and 5, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claim 12, it is believed that --receptin-- was intended. In this claim, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

Art Unit: 1641

In claim 14 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claims 29 and 30, "the" oligonucleotide lacks antecedent basis, it is believed claim -- 27-- was intended.

In claim 32, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claim 35 and claims dependent thereupon, "the" presence lacks antecedent basis.

In claims 36-38, "Kit" should be --The kit-- for proper reference to the previously recited claim components.

Claims 38-40 do not further limit any component(s) of the kit, as the claims appear to limit the intended use of the kit.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,

except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language;

Art Unit: 1641

Claims 1-10 and 32-40 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Self (US 4,595,655).

Self discloses sandwich assays for detection of a ligand using a non-antibody receptor to which the ligand naturally binds and the alternative mixed assay also using an antibody specific for the ligand. One of the pair of ligand binding molecules is labeled with a detectable marker and the other of the pair of ligand binding molecules is bonded to a solid support (see e.g. cols. 13-17). The reagents can be supplied in a kit (see e.g. col. 17).

Claims 1-8, 10, and 32-40 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Canfield et al. (US 5,284,778).

Canfield et al. disclose a sandwich assay for detection of a ligand using a non-antibody receptor to which the ligand naturally binds and an antibody specific for the ligand or the receptor-ligand complex. Either the receptor or the antibody can be labeled with a detectable marker (see e.g. col. 5). One of the pair of ligand binding molecules can be affixed to a solid support (see e.g. col. 7). The reagents can be supplied in a kit.

Claims 1-7, 9, 10, 32, 33, and 35-40 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Thompson et al. (EP 166,623).

Thompson et al. disclose a sandwich assay for detection of a ligand using a non-antibody lectin to which the ligand naturally binds and an antibody, or other specific binding moiety (see e.g. page 11), specific for the ligand. The lectin is preferably labeled with a detectable marker

Art Unit: 1641

(see e.g. page 7). The antibody or other binding moiety is preferably immobilized to a solid support such as a microtiter plate well (see e.g. pages 3, 8, or 19).

Claims 1-4, 6-8, 10-26, 32, and 35-40 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Hansson et al. (Immunotechnol. 4: 237, 1999).

Hansson et al. teach detection of binding to respiratory syncytial virus (RSV) G protein of a sandwich of anti-RSV monoclonal antibodies and an RSV G protein-binding affibody construct derived from a staphylococcal protein A Z domain/streptococcal protein G albumin binding domain fusion protein library. Either the antibody or affibody was immobilized on a sensor chip. The reference teaches that other suitable proteins used as scaffolds for combinatorial mutagenesis are available.

Claims 1-4, 6, 8, 10-26, 32, and 35-40 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Ljungqvist et al. (WO 00/63243).

Ljungqvist et al. teach detection of binding to human factor VIII of a sandwich of anti-factor VIII monoclonal antibodies and a human factor VIII-binding affibody construct derived from a staphylococcal protein A Z domain/streptococcal protein G albumin binding domain fusion protein library. The affibody was immobilized on a sensor chip. The reference teaches that other suitable proteins used as scaffolds for combinatorial mutagenesis are available.

Art Unit: 1641

Claims 1-4, 6-10, and 27-40 are rejected under 35 U.S.C. §§ 102(a) and 102(e)(1) as being clearly anticipated by Drukier (WO 01/81924).

Drukier discloses a sandwich assay for detection of a ligand using a non-antibody aptamer to which the ligand binds and an antibody specific for the ligand (see e.g. pages 11-12, 27, and 42-44; claims 43-62). Either the aptamer or the antibody can be labeled with a detectable marker. One of the pair of ligand binding molecules is affixed to a solid support chip.

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ljungqvist et al. (US 6,602,977) contains essentially the identical disclosure of Ljungqvist et al. (WO 00/63243).

Foresman et al. (US 5,801,064) disclose scFv-autoantigen-autoantibody sandwiches.

Samuel et al. (US 5,242,799) disclose lectin-antibody sandwich immunoassays.

Bosslet et al. (US 5,643,731) disclose universal solid phase or universal conjugate reagents in which pairs of leucine zipper peptides are bound to specific binding partners such as antibodies, lectins, receptors, etc. (see e.g. Figs.).

Art Unit: 1641

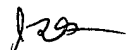
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

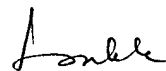
The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.
November 29, 2005



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12/09/05